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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,638	03/29/2004	Mario Abdennour	25669-014 CIP CON	3493
30623	7590 09/08/2005	EXAMINER		
•	VIN, COHN, FERRIS	BUMGARNE	BUMGARNER, MELBA N	
AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			ART UNIT	PAPER NUMBER
			3732	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
Office Action Summer.	10/812,638	ABDENNOUR ET AL.			
Office Action Summary	Examiner	Art Unit			
	Melba Bumgarner	3732			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 FR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1) Responsive to communication(s) filed on <u>26 July 2005</u> .					
· <u>-</u>					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
4) Claim(s) <u>1-27</u> is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
6) Claim(s) <u>1-27</u> is/are rejected.					
7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or election requirement.					
Application Papers	•				
9) The specification is objected to by the Examine	r.				
10) The drawing(s) filed on is/are: a) acce	epted or b) objected to by the E	Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:					
1. Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No					
3. Copies of the certified copies of the priority documents have been received in this National Stage					
application from the International Bureau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of the certified copies not received.					
Attachment(s)					
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date					
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)					
Paper No(s)/Mail Date 6) Uther:					

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DETAILED ACTION

Terminal Disclaimer

- 1. The terminal disclaimer filed on July 26, 2005 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of US patent no. 6,712,610 has been reviewed and is NOT accepted. Therefore, the nonstatutory double patenting rejection is maintained.
- 2. An attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34 (a). See 37 CFR 1.321(b) and/or (c).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-5, 7, 15-21, 23, and 27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,712,610. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between claims above of the application and claims 1-13 of the patent lies in the fact that the patent claim includes many more elements and is thus more

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specific. Thus the invention of the claims of the patent is in effect a "species" of the "generic" invention of the claims of the application. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 1-5, 7, 15-21, 23, and 27 are anticipated by claims 1-13 of the patent, they are not patentably distinct from the patented claims.

Claim Objections

5. Claims 9 and 13 are objected to because of the following informalities: recitation of "the antibiotic" in claim 9 and "the treatment site" in claim 13 lack sufficient antecedent basis.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

- 6. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 7. Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe a rigid copolymer vehicle nor rigid copolymer.
- 8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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9. Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by a "rigid copolymer vehicle" and "rigid copolymer".

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- Claims 1-3, 5, 6, 21, and 22 are rejected as understood, under 35 U.S.C. 102(b) as being anticipated by Goodson (4,892,736). Goodson discloses a fiber comprising a copolymer vehicle having incorporated therein one or more medicaments (column 3 line 30). Patentable weight is not given to the intended use of the fiber. It is noted that the fiber having the shape of a fiber having a diameter of about 0.1 to about 1mm would be suitable for placement in a root canal. As to claims 2 and 3, the medicament is antibiotic of tetracycline (column 6 line 37). As to claim 5, Goodson shows a combination of antibiotic and anti-inflammatory agent (column 6 line 53). Goodson shows the fiber impregnated with the medicament (column 3 line 26).

Claim Rejections - 35 USC § 103

- 12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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Goodson in view of Damani (5,114,718). Goodson discloses a fiber that shows the limitations as described above and the fiber is an ethylene vinyl acetate copolymer (column 4 line 63) having a diameter of 0.1 to about 1 mm; however, Goodson does not show medicament of clindamycin. Damani teaches devices providing medicament of clindamycin (column 2 line 65) as well as tetracycline (column 2 line 64). It would have been obvious to one having ordinary skill in the art to incorporate medicament of clindamycin to the fiber of Goodson, since Damani discloses both as known antibiotics. As to the dose of antibiotic, Damani teaches steady state average

concentrations of medicament of about 10 µg to 5000 µg per device.

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- 14. Claims 7-14 and 23-26 are rejected as understood, under 35 U.S.C. 103(a) as being unpatentable over Goodson. Goodson discloses obtaining a fiber having one or more medicaments incorporated therein that is suitable for intracanal use, positioning the fiber such that the fiber is in direct contact with a treatment site, and maintaining the fiber at the treatment site, wherein the medicament is delivered to the treatment site at a controlled rate (column 2 line 56), however, Goodson does not show the step of the fiber in the root canal. It would have been obvious to one of ordinary skill in the art to do so, since one skilled in the art would recognize that the fiber of Goodson is of a size and characteristics sufficient for positioning in a root canal and Goodson shows method of localized treatment within the oral cavity.
- 15. Claims 15-20 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodson in view of Hoyt et al. (4,003,810). Goodson discloses a fiber as described above and of ethylene vinyl acetate copolymer (column 4 line 63); however, Goodson does not show less than about 20% vinyl acetate. Hoyt et al. disclose a fiber (column 3 line 7) of ethylene vinyl acetate

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copolymer comprising 3 to 50 percent vinyl acetate. It is held to be an obvious matter of choice to one of ordinary skill in the art as to the specific amount of a known material and as to its

intended use.

Response to Arguments

16. Applicant's arguments filed July 26, 2005 have been fully considered but they are not

persuasive. Applicant's specification does not define a rigid fiber or a rigid copolymer.

Conclusion

17. Any inquiry concerning this communication or earlier communication from the examiner

should be directed to Melba Bumgarner whose telephone number is 571-272-4709. The

examiner can normally be reached on Mon-Fri.

Helba Bumguner

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Kevin Shaver can be reached at 571-272-4720. The fax phone number for the

organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melba Bumgarner

Primary Examiner